EXHIBIT 1

UNSIGNED PROPOSED COMPLAINT

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SAVANT NEGLECTED DISEASES, LLC *Plaintiff,* v. CHEMO RESEARCH S.L. and EXELTIS USA, INC., *Defendants.*	Case No: **COMPLAINT**

Plaintiff Savant Neglected Diseases LLC ("Savant") brings this action to remedy the harm from the scheme of Defendants Chemo Research S.L. ("Chemo Research") and Exeltis USA, Inc. ("Exeltis) to misappropriate and use highly-valuable data that was exclusively owned by Savant and which it had contributed to the joint development of a drug, benznidazole, for FDA approval in the treatment of Chagas disease. Using this pilfered data and the wrongful assistance of an Argentinean government employee that Defendants apparently bribed to ensure his cooperation, they managed to beat Savant and its faithless former partner, Humanigen, Inc. ("Humanigen"), in the race for FDA approval of benznidazole.

INTRODUCTION

1. Plaintiff Savant is a start-up drug manufacturer, originally formed by five longtime industry participants and largely self-funded, that has been pursuing FDA approval for benznidazole since 2011 to combat a severe shortage of drugs available to treat a parasitic infection, Chagas disease.

2. In late 2013, Savant entered into a license agreement with the Instituto de Efectividad Clínica y Sanitaria ("IECS"), an Argentinean academic institution, that granted Savant an exclusive, perpetual, and irrevocable license to the data from a 1998 double-blind, randomized trial on the use of benznidazole in the treatment of Chagas disease, which was conducted by Dr. Sergio Sosa-Estani (the "Sosa-Estani Study"). Based on its discussions with the FDA, Savant knew the Sosa-Estani Study would permit it would to gain FDA approval for benznidazole.

3. Subsequently, Savant worked to refine the formulation of benznidazole and commence preparatory work for the FDA submission.

4. During this period, Savant separately approached several potential partners about jointly-developing a benznidazole program for the United States. That included the corporate parent of Chemo Research and Exeltis, a large multinational pharmaceutical drug manufacturer, Chemo Group, that is now known as Insud Pharma ("Chemo"). It showed no interest.

5. However, in August 2015, the FDA added Chagas disease to the list of neglected tropical diseases that was eligible for a priority review voucher.

6. The priority review program was established in 2007 to create an economic incentive for pharmaceutical drug manufacturers to pursue treatments for diseases with small treatment populations in the United States, including rare pediatric diseases and neglected tropical diseases, where there is little to no chance of recovering development costs. If a manufacturer is first to gain FDA approval for a drug treatment for a select list of diseases, the manufacturer is granted a voucher that entitles the holder to expediated FDA review of a second drug for any type of disease.

7. Priority review vouchers are transferrable, and because they can significantly shorten the approval time for blockbuster drugs, they are worth in excess of $100 million—and have sold for as much as $350 million.

8. This development attracted attention to Savant's benznidazole project, which had been slowed by a lack of capital. It entered into a joint development agreement with a strategic partner, Humanigen, and was poised to make an FDA application in 2018.

9. The lure of a priority review voucher—and the nine-figure payday it would bring—also spurred Defendants to action. In or around February 2016, Chemo, and its charitable arm, Mundo Sano, entered into an agreement with and Drugs for Neglected Diseases Initiative ("DNDi"), a non-profit that works in this space, to seek FDA approval for benznidazole. Chemo committed to using its resources to manufacture and distribute benznidazole through its subsidiaries, Chemo Research and Exeltis, and DNDi agreed to procure data to support benznidazole's effectiveness as part of its commitment to this so-called "alliance." Chemo was to retain half of the value of the priority review voucher and the proceeds from sales of benznidazole, and DNDi and Mundo Sano were to receive the other half of the value of the priority review voucher.

10. When they entered into this agreement, Defendants were well aware of the existence of Savant's benznidazole project and its partnership with Humanigen, as well as the fact that the Sosa-Estani Study was central to their anticipated FDA application for benzindazole. Defendants therefore had only two options in their race to beat Savant-Humanigen to get FDA approval (and the voucher): Perform a costly new study that would take years to complete, or procure rights to the Study that had been exclusively licensed to Savant by whatever means necessary.

11. Defendants chose the latter option. Chemo and DNDi promised Chagas disease researchers and research institutions (like IECS) lucrative research grants if they would provide access to benznidazole data, and DNDi hired Sosa-Estani, at the time a government employee, as head of its Chagas disease initiative. In other words, they bribed a public official to obtain access to information he had no right to give them.

12. Publicly released FDA documents have confirmed that Defendants wrongfully misappropriated Savant's data. These documents demonstrate that Defendants had unfettered access to Sosa-Estani's assistance and the data from the Sosa-Estani Study, this data was submitted to the FDA as part of Defendants' benznidazole application, and the data and Sosa-Estani's help were instrumental in the FDA approving benznidazole for the treatment of Chagas disease.

13. The FDA approved benznidazole in August 2017 and awarded a priority review voucher to Chemo Research. In self-laudatory press releases and quotes, Chemo and DNDi have heaped praise on themselves for their collaboration and the charitable benefits that purportedly flowed from it.

14. However, the reality is that Defendants had *zero interest* in obtaining FDA approval for benznidazole in the treatment of Chagas disease until they saw the potential *profit* in it. Defendants simply misappropriated Savant's data and used it to deprive Savant of an opportunity that rightfully belonged to it.

15. Savant pleads the following claims against Defendants here.

PARTIES

16. Plaintiff Savant Neglected Diseases, LLC is a Delaware limited liability company with its principal place of business in Reno, Nevada.

17. Defendant Chemo Research S.L. is a Spanish corporation with its principal place of business in Madrid, Spain. In August 2017, the FDA approved Chemo Research's application for benznidazole in the treatment of Chagas disease in children ages two to twelve, and it awarded a priority review voucher to Chemo Research.

18. Defendant Exeltis USA, Inc. is a New Jersey corporation with its principal place of business in Florham Park, New Jersey.

19. Chemo Research and Exeltis are part of Chemo, which is a privately held pharmaceutical drug group that is based in Madrid, Spain with a presence in over 40 countries. Its social-responsibility activities are carried out through Mundo Sano, which is an organization based in both Spain and Argentina. While Chemo itself is not a company, its units operate as a coordinated group under a single global management.

JURISDICTION AND VENUE

20. Federal diversity jurisdiction exists pursuant to 28 U.S.C. § 1332 because Plaintiff is a Delaware company with its principal place of business in Nevada, Defendant Exeltis is a New Jersey corporation with its principal place of business in New Jersey, Defendant Chemo is a foreign entity, and the amount in controversy exceeds $75,000.

21. Federal jurisdiction also exists pursuant to 18 U.S.C. § 1836(b)(1) because Savant is the owner of a trade secret that was misappropriated and that is related to a product intended for use in interstate or foreign commerce.

22. This Court has personal jurisdiction over Defendants because the claims at issue are based in significant part on misconduct that took place in and emanated forth from New Jersey.

23. As set forth below, Chemo Research submitted a new drug application ("NDA") for benznidazole for the treatment of Chagas in pediatric patients. This application

was submitted to the FDA by Exeltis on behalf of Chemo Research on December 29, 2016, and was based, in significant part, on data wrongfully procured by DNDi and provided to Chemo Research and Exeltis to analyze. Documents made publicly available by the FDA indicate (1) the NDA was drafted, in whole or in part, by Exeltis in New Jersey using this stolen data; (2) Exeltis communicated from New Jersey with Chemo Research about the data and the NDA; and (3) Exeltis also communicated from New Jersey with the FDA about the data and the NDA. New Jersey was the jurisdictional hub that connected every aspect of Defendants' scheme.

24. As a result of Chemo Research's successful application, Exeltis is now distributing benznidazole from New Jersey and receiving profits from the sales of the drug that will inure to its benefit in New Jersey.

25. Venue in this district is proper pursuant to 28 U.S.C. § 1391 because a substantial part of the events on which the claims are based occurred in the District of New Jersey.

FACTUAL BACKGROUND

Savant Begins Work on its Benznidazole Project

26. Savant was co-founded in 2009 by Stephen Hurst, at that time its President and CEO, and Scott Freeman, its then Chief Medical Officer.

27. Hurst and Freeman each have worked in the biopharmaceutical industry for more than twenty years, and they joined forces to start a company with three other industry veterans.

28. The idea behind Savant was that the company would focus on areas with significant unmet medical needs that were being ignored by large pharmaceutical drug manufacturers, with a focus on addiction and select global health issues.

29. At the end of 2011, Savant[1] began to evaluate the potential for benznidazole as a treatment for Chagas disease, which is also known as American trypanosomiasis.

30. Chagas is a tropical parasitic infection that primarily affects people from rural parts of Latin America.

31. While the initial effects are in most cases mild, the chronic stage of the disease can result in severe damage to the sufferer's digestive system, heart, and nervous system. The number of sufferers worldwide are estimated to be in the range of 8 to 10 million. If left untreated approximately 30% of sufferers eventually die of heart failure.

32. At that time, benznidazole was one of only two drugs that had proven effective in treating Chagas disease, but there was a severe worldwide shortage of benzindazole. The drug had originally been developed by Roche, but it ceased production of the drug in 2006 and the remaining sources for benznidazole (Chemo, in Argentina, and DNDi/LAFEPE, in Brazil) were unreliable.

33. In addition, benznidazole had only been approved for treatment of Chagas in Argentina and Brazil, and other countries had to rely on compassionate use exemptions to acquire and distribute the drug.

[1] While the idea to develop benznidazole originated at Savant, Freeman formed a separate entity, Galenyx, to take the initial steps towards obtaining FDA approval. Galenyx sold the rights to the drug development program, including the License Agreement rights discussed below, back to Savant in 2013. For ease of reference here, we refer to both Savant and Galenyx as "Savant."

34. The economic value of benznidazole was limited by the fact that most Chagas sufferers live in poor, rural areas. Given this situation, the costs of getting regulatory approval for benznidazole, particularly by the FDA, were prohibitive.

35. Because the market in benznidazole in the United States was not large enough to justify the cost of development, it has not been commercially available in the United States, and it could only be acquired from the Centers for Disease Control on a patient-by-patient basis via an onerous application process.

36. These shortcomings led Savant to investigate the possibility of FDA approval for benznidazole through special FDA programs that might reduce the costs of development. No one else had come up with this approach.

37. In early 2012, Freeman began developing a regulatory and manufacturing strategy for seeking FDA approval for benznidazole in the treatment of Chagas disease.

38. As part of this strategy, Freeman reviewed the relevant literature and determined that there were two double-blind, randomized trials that showed benznidazole's efficacy in the pediatric treatment of Chagas disease: a 1996 study that had been conducted in Brazil by Dr. Ana Lucia De Andrade (the "De Andrade Study"), and a 1998 study that had been conducted in Argentina by Dr. Sergio Sosa-Estani (the "Sosa-Estani Study"). This was significant because these were randomized trials, which is the gold standard for demonstrating efficacy, and it would be unethical to conduct a new randomized trial. The reason for this is that since benznidazole is known to be effective in treating Chagas, it would be inappropriate to conduct a study where certain Chagas patients were randomly assigned a placebo.

39. The alternative to a randomized trial in demonstrating efficacy for benznidazole would have been a prospective clinical trial. However, conducting that type of

trial would take at least three years to complete, and it is considered less reliable than a randomized trial when seeking FDA approval. Accordingly, acquiring access to the data from these two studies was essential for a successful FDA application.

40. On or about May 29, 2012, Freeman started the process for getting FDA approval for benznidazole by submitting to the FDA background materials for a Pre-Investigational New Drug Meeting. The primary purpose of the Meeting was to confirm that the FDA would accept a 505(b)(2) application for benznidazole backed by the Sosa-Estani Study, which would allow the drug to be approved for treatment of Chagas in children based on the two existing randomized studies.

41. A 505(b)(2) application is a particular type of NDA, the name of which refers to a section of the Federal Food, Drug, and Cosmetic Act. The provisions of 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a drug previously approved by a regulatory authority; the section permits the FDA to rely on data not developed by the applicant. A 505(b)(2) application contains complete safety and effectiveness reports but certain of the information required for approval, such as safety and efficacy information on the active ingredient, comes from studies not conducted by or for the applicant.

42. On or about June 29, 2012, the Investigational New Drug Meeting took place between Freeman and representatives of the FDA.

43. In the course of that Meeting, the FDA confirmed that it would be willing to accept a 505(b)(2) NDA for benznidazole. However, the FDA also made clear that it would need patient-level data to analyze and review (which would only be available from the

researchers), and it would not be satisfied with merely published or excerpted data, therefore, the FDA would need the patient-level data from the Sosa-Estani Study.

The FDA Adds Chagas to the List of Neglected Diseases that Could Entail a Priority Review Voucher, thus Changing the Economics of Developing Benznidazole

44. In 2007, the FDA established a priority review voucher program for neglected tropical diseases. The program was created to encourage drug companies to develop treatments for drugs that might otherwise not be profitable to develop because of the relatively small pool of potential patients.

45. Under the program, if a pharmaceutical drug manufacturer successfully develops and obtains the first FDA approval for a drug treatment of an eligible disease or condition, it is then granted a priority review voucher that can be used to expedite the approval process of another drug.

46. The value of a voucher lies in the fact that it is transferrable, and that an expedited FDA approval process can save a manufacturer millions in development costs, while allowing it to earn millions more by bringing a drug to market more quickly and extending the sales period while the drug is still under patent protection.

47. While the monetary value of a priority review voucher was uncertain in 2011, when Savant started work on its benznidazole project, the value has proven to be considerable. In July 2014, BioMarin sold the first priority review voucher to Sanofi and Regeneron for $67.5 million. The next year Retrophin sold a voucher to Sanofi for $245 million, and United Therapeutics sold a voucher to Abbvie for $350 million. Most recently, priority review vouchers have sold for in excess of $100 million.

48. When Savant commenced its benznidazole project, there was almost no interest in the drug.

49. Savant approached Chemo in May 2013 about working together to get FDA approval for benznidazole. An initial meeting took place in Buenos Aires at which Savant offered, among other things, to split the costs of development with Chemo and to transfer its benznidazole technology to Mundo Sano for charitable use in Latin America. However, Chemo had no interest in this collaboration.

50. This lack of enthusiasm for benznidazole was shared by non-profits, including DNDi. Savant reached out to DNDi in 2013 about forming a partnership to seek FDA approval for benznidazole. DNDi declined this offer. According to DNDi, it was not interested in existing treatments for Chagas disease, like benznidazole.

Savant Licenses the Sosa-Estani Study

51. Encouraged by the FDA's receptiveness to a 505(b)(2) NDA, Freeman reached out to the investigators behind the two benznidazole studies to determine if the data was sufficiently robust to serve as the basis for an application. With respect to the De Andrade Study, the primary investigator explained that the data had been saved to a floppy disk and was no longer retrievable, and that the study had concluded in 1998 and had not been updated since. Freeman contacted another investigator on the De Andrade study who expressed doubts about the quality of the data.

52. As for the other study, Freeman learned that Dr. Sosa-Estani had continued his research in Chagas up through the present day, making his study, and expertise, all the more valuable. Sosa-Estani was initially uninterested in working with Savant, but following additional discussions, he relented. He offered to license the data to Savant as part of a research collaboration.

53. Sosa-Estani sent Freeman a proposal for a research project that would require approximately $44,000 in funding, to be paid in four quarterly installments. Savant agreed to this proposal and negotiated two agreements with Sosa-Estani: a License Agreement, for exclusive use of his benznidazole data, and a Research Agreement, to fund Sosa-Estani's research proposal. Sosa-Estani informed Freeman that the contracts would be between Savant and IECS, which is an academic institution affiliated with the Buenos Aires School of Medicine that has a relationship with Sosa-Estani. He put Freeman in direct contact with IECS to finalize the terms. Savant began making payments to IECS for the sponsored research project before either contract was signed to move the process forward.

54. Subsequently, Freeman went to Argentina to meet with Sosa-Estani and to confirm the quality of the data from the Sosa-Estani Study. Freeman determined the trial was double-blind, involving 106 children, aged six to thirteen years, who were followed for 48 months following treatment with benznidazole and a placebo.

55. On May 24, 2013, Freeman sent Sosa-Estani an email in which he offered to purchase the data from the Sosa-Estani Study. He explained that Savant would like to use every patient from the study, if possible, and it would pay for access on a per patient basis. Sosa-Estani would retain the right to use the data for his academic or scientific endeavors. Freeman asked Sosa-Estani to inform him if these conditions were acceptable, so that he could send a formal contract.

56. Shortly thereafter, Sosa-Estani accepted Freeman's offer to purchase the database: "Yes Scott, I agree with your proposal." There was further email correspondence in which Sosa-Estani confirmed that the contract memorializing this agreement should also be between Savant and IECS.

57. Following this exchange, Savant sent IECS (and Sosa-Estani) drafts of the agreement for the research project (the "Sponsored Research Agreement") and the agreement for an exclusive license to the Sosa-Estani Study database (the "License Agreement"). There was no negotiation concerning the contractual provisions. As the parties had already agreed to the material terms and were performing, executing the contracts was a mere formality.

58. On or about September 17, 2013, a representative of IECS emailed Savant, copying Sosa-Estani, indicating that the "two agreements . . . for us are accepted. If you need to send them signed, please let me know." Savant sent copies of the Agreements to IECS for execution.

59. On or about December 5, 2013, Adolfo Rubenstein, Director General of IECS, signed both Agreements for IECS and sent them to Savant, along with an invoice for the third installment payment due under the Sponsored Research Agreement. By this time, Savant had made two of the four payments contemplated under the Sponsored Research Agreement. Savant counter-signed the Sponsored Research Agreement and the License Agreement and mailed both Agreements to IECS.

60. The License Agreement has an effective date of August 23, 2013, which reflects the fact that contract was fully in force before it was even signed. The License Agreement grants Savant an exclusive, perpetual, and irrevocable license in the "Data Products," which is defined broadly to include the Sosa-Estani Study and related present and future intellectual property. In addition, the License Agreement mandates that IECS:

> (a) may not grant any license to any other person of the Data Products for the Exclusive Use, in whole or in part, (b) reserves no rights in the Data Products for the Exclusive Use to itself or its affiliates, and (c) may not assign transfer or otherwise dispose of the Data Products, except as part of an assignment of this Agreement in its entirety in accordance with Section 2.6.

61. Pursuant to the License Agreement, IECS also represented and warranted that it would not "take any actions that would result in or omit to act resulting in the termination of the rights granted to Savant under this Agreement," as well as that "Savant has the exclusive right to use the data for regulatory filings in the United States and Europe."

62. Following the parties' entry into the License Agreement and the Sponsored Research Agreement, IECS and Savant corresponded multiple times about the results of the research project. Savant also made payments under the Sponsored Research Agreement on or about March 22, 2013, September 19, 2013, February 10, 2014 and October 2, 2014. Several of these payments were made by Savant by mail to IECS, just as it did with respect to the two Agreements.

63. On or about February 13, 2015, IECS contacted Freeman and stated that it could not locate a counter-signed copy of the License Agreement. Freeman was surprised by this statement because it had been approximately fourteen months since Savant had sent the two Agreements to IECS, and the latter had never said anything about not having received a counter-signed copy of the License Agreement. Nor had it ever claimed before, at the time, or since to be missing the Sponsored Research Agreement—which had been sent at the same time and was the basis for the four payments Savant made to IECS. Nevertheless, Freeman emailed Hurst, copying IECS, and asked Hurst to send IECS the fully-executed version.

64. A few days later, Hurst emailed a scanned copy of the License Agreement to IECS. Savant heard nothing back from IECS that would indicate it had not received the scanned copy of the License Agreement.

Savant forms a Strategic Partnership to Facilitate an FDA Application

65. During 2014 and the first part of 2015, Savant focused on manufacturing benzindazole, which was the next step in seeking FDA approval. It developed a manufacturing process that produced benznidazole that was more than 99% pure, as opposed to the approximately 97% pure benznidazole that was being produced by other manufacturers. However, Savant was hamstrung by a lack of resources. As a result of the high costs associated with seeking regulatory approval relative to the benznidazole's economic potential, Savant was unable to attract either capital or a strategic partner for the benznidazole project.

66. The landscape shifted in August 2015, when the FDA added Chagas to the list of neglected tropical diseases that were eligible for a priority review voucher. While this was the development that Savant had been awaiting, it was not in position to take advantage of the opportunity on its own. The company had failed to secure a grant for another drug and it was rapidly running out of money.

67. Around this time Savant was approached about benznidazole by a group of investors led by the infamous Martin Shrkeli, who became the poster-child for overpriced drugs when in the summer of 2015 the Shkreli-lead Turing Pharmaceuticals purchased an infection-fighting drug for HIV patients and hiked the drug's price.

68. Savant rebuffed Shrkeli because it had concerns about his reputation in the drug industry, but the company had limited alternatives given its desperate financial situation. In November 2015, Shrkeli's group acquired a majority stake in Humanigen, a publicly-traded pharmaceutical drug manufacturer, and turned its attention back to Savant.

69. While Humanigen's discussions with Savant were still in the preliminary stages, Shkreli made his intentions for benznidazole clear. As was publicly reported in a *New*

York Times article dated December 11, 2015, Shrkeli planned to have Humanigen price benznidazole at levels close to Hepatitis-C antivirals, which would have been a massive increase in the price of the drug compared to what it was being sold for in Argentina and Brazil. This came as an utter shock to Savant, which had no prior knowledge of Shrkeli's plan before he announced it.

70. Almost immediately after making these statements, and long before Savant finalized a deal with Humanigen, Shrkeli was fully and unequivocally removed from the picture: On December 17, 2015, Shrkeli was arrested on securities fraud charges; on December 18, Humanigen terminated his employment and removed him from its Board of Directors; and approximately two weeks later, Humanigen filed for Chapter 11 bankruptcy protection. In August 2017, Shrkeli was found guilty of securities fraud related to two hedge funds that he ran, and he was subsequently sentenced to seven years in prison.

71. After Savant's brief experience with Shrkeli ended permanently, Humanigen management took steps to ensure that benznidazole would be reasonably priced if the company's NDA for the drug was granted. In April 2016, Humanigen announced a fair pricing pledge, by which its products would be priced at its cost plus a reasonable and transparent margin. When the company emerged from bankruptcy three months later and subsequently renamed itself Humanigen, it reconfirmed its fair pricing pledge. This pledge was fully supported by Savant, which at all times planned for benznidazole to be reasonably priced.

72. In March 2016, Savant contacted Sosa-Estani and IECS to provide access to the database as required by the License Agreement. Since Savant was in the process of finalizing a contract with Humanigen, it needed access to the patient-level data to begin the preparatory work for a NDA. In response, Sosa-Estani refused to do so. He claimed that

Savant's last correspondence had been in September 2014, and that IECS had "not received any response from you after communication for technical and administrative issues." Based on this purported lack of communication, he and IECS supposedly assumed Savant was no longer interested in data from the Sosa-Estani Study.

73. Subsequently, IECS sent Savant a letter in which it claimed that the License Agreement was invalid.

74. Not only were these assertions plainly wrong, but they were preposterous on their face. The timing was also suspicious in that Sosa-Estani and IECS only raised them after the FDA had approved Chagas Disease as eligible for a priority review, and after IECS had received the $44,000 in research funding promised under the contemporaneously-executed Research Agreement. Savant was concerned that Sosa-Estani and IECS were attempting to sell the Sosa-Estani Study to a higher bidder. Savant informed Humanigen of the situation, and put Cameron Durrant, Humanigen's President and CEO, in direct contact with Sosa-Estani to negotiate a resolution.

75. Following discussions between Humanigen and Sosa-Estani, the latter appeared to change his mind. On June 16, 2016, Sosa-Estani confirmed by email that he would provide Humanigen with the information it required, he would meet with its representatives in Argentina to audit his data, and he would otherwise assist with the Savant-Humanigen FDA application as needed. Sosa-Estani closed this exchange by noting that he "hope[d] our collaboration will be useful[]."

76. On or around June 30, 2016, just before Humanigen emerged from bankruptcy, and after Durrant met with Sosa-Estani to resolve the dispute over his data, it and Savant executed the Agreement for the Manufacture, Development and Commercialization of

Benznidazole for Human Use (the "MDC Agreement").[2] At Savant's insistence, the MDC Agreement includes a provision by which Savant has the right to promptly terminate the contract if Shrkeli's has any involvement with Humanigen.

77. Under the MDC Agreement, Savant transferred its rights to benzindazole, the Sosa-Estani Study, and any related FDA documentation to Humanigen in exchange for Humanigen making an initial payment of $3,000,000, a series of "Milestone Payments" ranging from $1,000,000 to $11,000,000, and granting Savant a right to 20% of the proceeds of the sale of any voucher issued by the FDA.

78. These Milestone Payments were keyed to important events in the drug development lifecycle. Humanigen agreed to pay $1 million when the FDA accepts the benznidazole preliminary NDA, another $1 million when the FDA grants "Orphan Drug Designation" to benzindazole, $2 million when the FDA accepts a formal NDA, $11 million when the FDA grants approval, and so forth.

79. The MDC Agreement can be terminated "for cause" if either party materially breached its terms. Section 13.3(a) provides that the non-breaching party may terminate for cause "in the event the other party . . . shall have materially breached or defaulted in the performance of its obligations under the Transaction Documents and such breach or default shall have continued for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-Breaching Party."

80. If Savant terminates the MDC Agreement for cause, Section 13.6(d) provides that "all rights and licenses granted to [Humanigen] under this Agreement shall terminate,"

[2] This contract was signed while Humanigen was still known as Kalobios. For the sake of consistency, we refer to it as the "MDC."

and Humanigen "shall transfer to [Savant] all right, title and interest in and to" the benzindazole-related assets.

81. In short, Humanigen agreed to pay considerable sums of money to Savant in exchange for access to the valuable Sosa-Estani Study and the right to develop and sell benzindazole, but if it failed to meet its obligations, all rights to the study and the drug itself reverted to Savant.

Defendants Hatch Their Benznidazole Scheme

82. When the FDA added Chagas disease to the list of neglected tropical diseases, it attracted other entities to the possibility of getting regulatory approval for benzindazole. In or around February 2016, Chemo, DNDi, and Mundo Sano entered into a joint venture agreement to work together to seek FDA approval for the drug. Chemo committed to applying for FDA approval and, if successful, selling benznidazole through its subsidiaries.

83. In turn, DNDi committed to providing "technical and scientific expertise" to Chemo, as well as "data gathered with partners from previous clinical trials for adult and paediatric forms."

84. At this time, Defendants knew that the Sosa-Estani Study was crucial to a successful pediatric indication for benznidazole, and that Savant had exclusive rights to data from the Study. Chemo has acknowledged its awareness of the Sosa-Estani Study.

85. According to a declaration from Exeltis' Head of Regulatory Affairs that was filed in another litigation, "Dr. Sergio Sosa-Estani is one of the leading Chagas disease researchers in the world. Chemo Research has been familiar with his important 1998 study on the effects of pediatric Chagas for years."

86. Defendants also knew that Savant had obtained an exclusive license to the data from the Sosa-Estani Study. To begin with, when Savant met with Chemo in Buenos Aires in May 2013, Freeman told Silvia Gold (one of the co-founders of Chemo and the head of Mundo Sano) and Luis Ferrero (a representative of Chemo's Argentinian subsidiary) that he was working with Sosa-Estani in connection with Savant's efforts to obtain FDA approval for benznidazole.

87. Further, publicly available information put Defendants on notice that Savant-Humanigen were planning to rely on the Sosa-Estani Study in their NDA. In press releases and articles, Defendants have repeatedly referenced a Humanigen investor presentation on benznidazole that was part of an SEC filing.

88. This December 2015 presentation states that (1) Humanigen had entered into a preliminary agreement with Savant to acquire the "worldwide rights to Savant's benznidazole program;" (2) the program was based on a 505(b)(2) application for benznidazole using existing trials on efficacy; (3) the FDA had preliminarily agreed with Savant that no new clinical trials related to efficacy would be required; and (4) Savant believed the Sosa-Estani Study showed that a "60-day course of treatment leads to long-term parasitological cure in majority (>60%) of acute phase patients." On information and belief, the FDA also informed Chemo about the critical importance of the Sosa-Estani Study to obtaining approval for the drug. The inescapable conclusion to be drawn from this information is that Defendants knew the Sosa-Estani Study was the centerpiece of Savant's benznidazole program and would be used in the anticipated NDA application.

89. Defendants are highly sophisticated entities that are versed in the customs and conventions in the pharmaceutical drug industry. They would have therefore been aware that

when a company is anticipating making a 505(b)(2) application, it is customary and expected to get an exclusive license to the relevant clinical data. Otherwise, the company risks investing years of effort and substantial resources in seeking FDA approval only to have that opportunity usurped by a competitor.

90. Despite Defendants' knowledge that Savant possessed an exclusive license to the data from the Sosa-Estani and the existence of the MDC Agreement, as well as the importance of the underlying data to Savant-Humanigen's benznidazole project (since, according to public records, they too were told by the FDA that the data was critical), they moved forward with their clandestine plan to secure use of the Sosa-Estani Study to support their own FDA application.

91. They proceeded to misappropriate data that belonged to Savant and to wrongfully procure IECS's breach of the License Agreement and Sosa-Estani's cooperation.

92. A South American scientist has informed Savant that DNDi broadly reached out to researchers in an effort to secure exclusive rights to their data on benznidazole trials. DNDi offered to create a so-called "financial consortium," whereby the researchers and their institutions would receive valuable research grants in exchange for the rights to their clinical data. DNDi promised that these research grants would be funded from the tens of millions it would receive from the sale of the FDA priority review voucher.

93. On information and belief, Chemo and DNDi offered Sosa-Estani a similar financial incentive to breach the License Agreement.

94. Defendants did not stop there. In December 2016, DNDi hired Sosa-Estani to be the Head of its Chagas Clinical Programme, which is a leadership and highly compensated position within the organization. Among other benefits, this position put Sosa-Estani in place

to direct research grants to IECS and its researchers. Given Sosa-Estani's critical importance to Defendants' scheme, Chemo and DNDi apparently decided to pay Sosa-Estani directly so that he would breach the License Agreement and conceal that fact from Savant and Humanigen.

95. None of this was known to Savant. While Sosa-Estani's false contentions about the validity of the License Agreement had been suspicious, the issue had seemingly been resolved in June 2016.

96. Humanigen did extensive due diligence prior to entering into the MDC Agreement, which included direct discussions with Sosa-Estani. Following the parties' entry into the MDC Agreement, Humanigen took the lead on interacting with Sosa-Estani in furtherance of the benznidazole NDA. It reported no issues to Savant concerning his cooperation.

Defendants Use Savant's Data to Get FDA Approval

97. On December 29, 2016, Exeltis submitted on Chemo Research's behalf a NDA for benznidazole in the treatment of Chagas disease in pediatric patients, age 2 to 12. It was submitted from Exeltis' headquarters in Floral Park, New Jersey. Publicly available documents demonstrate that the Sosa-Estani Study, including data that Defendants could have only acquired from Sosa-Estani himself, was the central component of this application.

98. According to the declaration filed by Exeltis' Head of Regulatory Affairs, in May 2016 Chemo Research contacted a research institution that is overseen by Sosa-Estani about the Sosa-Estani Study.

99. The research institution, presumably with the full knowledge and blessing of Sosa-Estani, provided Chemo Research with data from the Study. But there were problems

with the data that was available from the institution. To correct this issue, Sosa-Estani provided supplemental data directly to Chemo Research.

100. As set forth in the FDA's Summary Review of the NDA, Chemo Research and Exeltis submitted "source data" (*i.e.*, patient-level data) from the Sosa-Estani Study to the FDA in connection with their submission.

101. This is the information that the FDA had informed Savant was necessary for a successful application, which presumably the FDA explained to Chemo Research and Exeltis as well.

102. According to an August 2, 2017 Clinical Inspection Summary, Chemo Research also made its written correspondence with Sosa-Estani available to the FDA for review. The FDA found that this correspondence was supportive of Chemo Research's application.

103. Sosa-Estani even permitted the FDA to conduct an on-site audit of his files and records. As set forth in the FDA's Clinical Inspection Summary, this audit took place over July 7-10, 2017, and it included a detailed review of the patient files and verbal discussions. Based on the information provided, the FDA concluded that any deficiencies in the study did not implicate its clinical findings. The importance the FDA attached to this inspection puts the lie to Defendants' assertions that the data supporting the Sosa-Estani Study was publicly available as a matter of Argentinean law; had the full breadth of information deemed relevant by the FDA been available, there would have been no need for it to conduct this thorough on-site inspection.

104. On August 29, 2017, the FDA granted conditional and accelerated approval of Chemo Research-Exeltis application, and awarded the valuable priority review voucher to Chemo Research.

105. The FDA's records demonstrate that the Sosa-Estani Study was crucial to the success of Chemo Research's NDA for benznidazole in the treatment of children ages two to twelve. Of the four trials that Chemo Research used to support its application, only the results of the Sosa-Estani Study were audited by the FDA.

106. In addition, in its Summary Review the FDA noted that two of the four trials were of limited value because they were not conducted on children and had structural shortcomings.

107. Given the weight that the FDA placed on the Sosa-Estani Study, it is evident that the FDA would not have approved Chemo Research's application without access to patient-level data from the Sosa-Estani Study that rightfully belonged to Savant.

Savant Recovers the Rights to Benznidazole and the Sosa-Estani Study

108. After losing the race to FDA approval because of Defendants' cheating, the relationship between Savant and Humanigen collapsed. While Humanigen and the parties related to it have erroneously claimed to hold most (but not all) of the rights to benznidazole and the property that Defendants stole, that issue is being resolved by a Delaware court. Savant's ownership claim is superior, and even if it was not, Humanigen and Madison have conceded in the Delaware action that they cannot object to Savant pursuing its claims against Defendants.

109. Humanigen learned during the summer of 2017 that Chemo Research and Exeltis were on the verge of obtaining FDA approval for benznidazole.

110. Humanigen kept this information from Savant, who was supposed to be its partner in the drug's development. On information and belief, it also proceeded to cease working on its FDA application as soon as it became aware that Chemo was weeks away from obtaining FDA approval.

111. But-for Chemo's interference and wrongful appropriation of the Sosa-Estani Study, Humanigen would have completed the process, paid Savant over $20,000,000 in milestone payments, paid Savant 20% of the Voucher's value, and paid 15% of the sales to Savant in perpetuity.

112. On the day the FDA announced that Chemo Research-Exeltis had won the race for FDA approval of benznidazole, Humanigen made a public filing in which it stated that it was "assessing its options" with respect to its benznidazole development program.

113. This was a guarded way for Humanigen to disclose that it had ceased all efforts to develop benznidazole (which it had surreptitiously ended in or around July, when it learned Chemo would get FDA approval). It began the first phase of the Delaware litigation shortly thereafter, suing Savant for alleged cost overruns in the benznidazole development process. Savant counterclaimed for the millions of dollars in milestone payments Humanigen owed it but refused to pay.

114. To be clear, Humanigen's abandonment of its obligations under the MDC means that any rights it once possessed in the Sosa-Estani data have reverted to Savant. Nevertheless, this did not stop Humanigen from attempting to monetize its purported interest in a lawsuit against Chemo.

115. In December 2017, Humanigen announced it was selling its interests in benznidazole under the MDC Agreement and all related legal claims to a shell entity, Madison

Joint Venture ("Madison"), for the purpose of satisfying Humanigen's outstanding debt obligations to Madison's majority owner, Nomis Bay. Humanigen also received a 30% interest in Madison, which means it stood to profit from any legal claims pursued by Madison.

116. On June 4, 2019, Savant filed a new complaint in Delaware setting forth Humanigen's manifold breaches of the MDC Agreement, and which seeks a declaration that the interests in the Sosa-Estani Study and benznidazole that it contributed to the venture with Humanigen have fully reverted to it. This new action was consolidated with the earlier Milestone Payments case (collectively, the "Delaware Litigation"). The Delaware Litigation will confirm that Savant is the lone party with standing to assert claims against Defendants. Savant is entitled to a recover against Defendants for their brazen theft of a project that it conceived of and has pursued since 2011.

CAUSES OF ACTION

COUNT I
Tortious Interference with Contract (License Agreement)

117. Plaintiff repeats and realleges, as if set forth fully herein, the allegations in the preceding paragraphs of this Complaint.

118. Under New Jersey law, a defendant is liable for tortious interference with contract when (i) there is an existing contractual relationship; (ii) they intentionally and maliciously interfere with that relationship; (iii) the interference results in a loss or a breach of the contract; and (iv) plaintiff suffers damages as a result.

119. First, there were existing contracts. Savant and IECS signed the License Agreement in December 2013, which granted Savant exclusive rights to use the Sosa-Estani Study for FDA regulatory filings. These rights were granted in perpetuity, and no provision of the License Agreement could be waived absent the written agreement of the parties.

120. Defendants became aware that the License Agreement was in effect no later than the end of 2015. Savant informed Defendant Chemo Research (via Chemo and Mundo Sano) in May 2013 that it was pursuing the Sosa-Estani Study for use in an application for FDA approval of benzindazole; Exeltis later confirmed that Chemo Research had been aware of the importance of this study for years. Indeed, Savant understands that the FDA informed Chemo Research about the importance of the Sosa-Estani Study.

121. Second, Defendants intentionally and maliciously interfered with the License Agreement. Humanigen's December 2015 investor presentation, filed publicly with the SEC, revealed that (1) Humanigen had entered into a preliminary agreement with Savant to acquire the "worldwide rights to Savant's benznidazole program;" (2) the program was based on a 505(b)(2) application for benznidazole using existing trials on efficacy; (3) the FDA had preliminarily agreed with Savant that no new clinical trials related to efficacy would be required; and (4) Savant believed the Sosa-Estani Study showed that a "60-day course of treatment leads to long-term parasitological cure in majority (>60%) of acute phase patients."

122. Further, as sophisticated entities researching treatments for Chagas, they must have known that the Sosa-Estani Study was the only existing trial (given the inaccessibility of the De Andrade data) capable of supporting a 505(b)(2) application. Moreover, as successful pharmaceutical drug companies familiar with the FDA approval process, they must have been aware that it was the custom and practice in the industry to secure exclusive rights to use such studies in FDA applications—otherwise, the applicant runs the risk of a competitor beating them to the finish line.

123. Third, the interference resulted in a breach of the contract. In February 2016, Chemo Research partnered with DNDi to pursue FDA approval of the drug, with Exeltis acting as their agent. Chemo Research's knowledge is therefore imputed to Defendant Exeltis.

124. Defendants then maliciously and intentionally procured IECS's breach of the License Agreement, and Sosa-Estani's misbehavior, by signing their own agreement with IECS and Sosa-Estani, paying them what appears to be far more money than they received under the License Agreement, and sweetening the deal by having DNDi hire Sosa-Estani for a plum research position.

125. Defendants had two specific goals in signing their own agreement, both of which demonstrate malice. First, they wanted the voucher that would accompany FDA approval of benznidazole as a Chagas treatment, which they could then sell for hundreds of millions of dollars. They needed access to the Sosa-Estani data to secure that approval, and could not get it without inducing IECS to breach their exclusive License Agreement with Savant. Second, they specifically wanted to keep benznidazole (and the benefits that flow from FDA approval) away from Humanigen, purportedly to prevent price-gouging by its one-time owner, Martin Shkreli. This goal, however noble-sounding, is belied by the facts: Shkreli was removed from Humanigen *before* DNDi and Chemo Research agreed to join forces, and Humanigen then pledged publicly in the spring of 2016 that it would only sell its drugs at a reasonable price. What's more, Defendants had previously rebuffed Savant when it proposed developing benznidazole for FDA approval in 2013—prior to the voucher being made available for treatments for Chagas disease. Had Defendants' motives been as pure as now advertised, they would have agreed to a joint endeavor with Savant years ago.

126. By signing an agreement with DNDi and Chemo Research, IECS breached its obligations under the License Agreement to provide the Sosa-Estani Study data only to Savant for regulatory filings, for Savant's exclusive use.

127. Finally, As a result of this tortiously-induced breach, Savant suffered significant damages. There can be no dispute that the Sosa-Estani Study was the lynchpin of FDA approval of benzindazole; the FDA has said as much. By obtaining exclusive (and, later, once the damage had been done, joint) access to the Sosa-Estani Study, Defendants ensured that they, not Savant, would be the ones to obtain FDA approval, and the voucher that came with it. On the open market, these vouchers have been valued at between $100 million and $350 million.

128. Plaintiff is thus entitled to receive damages equivalent to the loss of the voucher as a result of Defendants' tortious interference with the License Agreement in an amount to be determined at trial, of not less than $200 million.

COUNT II
Tortious Interference with Contract (MDC Agreement)

129. Plaintiff repeats and realleges, as if set forth fully herein, the allegations in the preceding paragraphs of this Complaint.

130. As explained above, a defendant is liable for tortious interference with contract under New Jersey law when (i) there is an existing contractual relationship; (ii) they intentionally and maliciously interfere with that relationship; (iii) the interference results in a loss or a breach of the contract; and (iv) plaintiff suffers damages as a result.

131. On or around June 30, 2016, Humanigen and Savant executed the MDC Agreement, which set forth the terms of their joint program to develop benznidazole and seek FDA approval for the drug. Under the MDC Agreement, Savant transferred its rights to

benznidazole, the Sosa-Estani Study, and any related FDA documentation to Humanigen in exchange for Humanigen making an initial payment of $3,000,000, a series of "Milestone Payments" ranging from $1,000,000 to $11,000,000, and granting Savant a right to 20% of the proceeds of the sale of any voucher issued by the FDA.

132. The Milestone Payments were keyed to significant events in the drug development lifecycle. Humanigen agreed to pay Savant, among other things, $1 million when the FDA accepts the benznidazole preliminary NDA, another $1 million when the FDA grants "Orphan Drug Designation" to benznidazole, $2 million when the FDA accepts a formal NDA, and $11 million when the FDA grants approval.

133. First, Defendants were well aware of the existence of the MDC Agreement. They knew that Savant had been looking for a drug development partner for years. Moreover, in December 2015, Humanigen filed a publicly-available investor presentation with the SEC disclosing the existence and goals of its joint benznidazole development program with Savant. Defendants have regularly cited and quoted from this investor presentation, indicating knowledge of its terms.

134. Second, Defendants intentionally interfered with the MDC Agreement. They misappropriated the Sosa-Estani Study and used it to obtain FDA approval of benznidazole before Savant and Humanigen, which had the predictable, logical, and desired effect of causing Humanigen to terminate its benznidazole development program and default on its obligations to Savant. This included failing to make millions of dollars in Milestone Payments, and failing to market any version of benznidazole, denying Savant its 20% of the sale proceeds of the drug that the MDC Agreement promised.

135. Third, this interference was malicious. It was procured by Defendants' wrongful misappropriation of the Sosa-Estani Study and done expressly to deny Savant and Humanigen the valuable priority review voucher.

136. Finally, Savant suffered damages as a result of Defendants' interference. Humanigen has refused to pay millions of dollars in Milestone Payments that Savant is owed, and is not marketing benznidazole, which denies Savant its 20% share of the sale proceeds of the drug.

137. Plaintiff is thus entitled to receive damages for the lost Milestone Payments and lost sale proceeds in an amount to be determined at trial, of not less than $21 million

COUNT III
Misappropriation of Trade Secrets

138. Plaintiff repeats and realleges, as if set forth fully herein, the allegations in the preceding paragraphs of this Complaint.

139. Under New Jersey law, a defendant is liable for misappropriation of trade secrets when they use a plaintiff's trade secrets without consent, and knew or had reason to know that the trade secrets were obtained through improper means.

140. There is no doubt that the data underlying the Sosa-Estani Study constitutes a trade secret. While the results of the study were widely publicized, Sosa-Estani and IECS zealously guarded the underlying, patient-level data for years. Without this data, it would have been futile to pursue FDA approval for benzindazole.

141. By signing the License Agreement, IECS gave Savant exclusive rights to this valuable data, which became Savant's trade secret. Savant did not disclose this data to others, and maintained its secrecy.

142. Savant never authorized any of the Defendants to have access to the Sosa-Estani Study data. Nevertheless, by inducing IECS to breach the License Agreement and give them access to the data by improper means (as described above), Defendants were able to obtain Savant's trade secrets.

143. As a result of this misappropriation, Plaintiff could not obtain FDA approval of benzindazole, and lost the chance to obtain a valuable priority review voucher.

144. Plaintiff is thus entitled to receive damages for the loss of the voucher as a result of Defendants' misappropriation of the Sosa-Estani Study data in an amount to be determined at trial, of not less than $200 million.

COUNT IV

Violation of the Defend Trade Secrets Act, 18 U.S.C. § 1836 *et seq.*

145. Plaintiff repeats and realleges, as if set forth fully herein, the allegations in the preceding paragraphs of this Complaint.

146. The Defend Trade Secrets Act ("DTSA") creates a federal private right of action for the misappropriation of trade secrets related to a product used or intended to be used in interstate or foreign commerce.

147. The DTSA authorizes equitable relief, including injunctions requiring steps be taken to protect the trade secret, and, when appropriate, conditioning future use of the trade secret on royalty payments. It also authorizes money damages for actual losses, any amounts by which the wrongdoer has been unjustly enriched, or unpaid royalties. Where the wrongdoer acted with malice, the DTSA authorizes exemplary damages of up to double those amounts.

148. The Sosa-Estani Study is a trade secret owned by Savant because it is business and scientific information that both Savant and IECS kept secret, and it derives independent economic value from not being known to others who could themselves obtain economic value

from using or disclosing it. When Defendants did, in fact, disclose the data, without permission from Savant, they obtained a voucher worth hundreds of millions of dollars that should have rightfully gone to Plaintiff.

149. Defendants misappropriated the Sosa-Estani Study because they acquired it by improper means. They improperly induced IECS to breach their exclusive License Agreement with Savant and share the Sosa-Estani Study with them. This constitutes the "inducement of a duty to maintain secrecy" under the DTSA.

150. This misappropriation was malicious. Defendants needed the Sosa-Estani Study to secure the voucher that would accompany FDA approval of benznidazole as a Chagas treatment, which they could then sell for hundreds of millions of dollars. Knowing that IECS had an exclusive License Agreement with Savant, Defendants intentionally induced IECS to breach that agreement. Likewise, they claim to have wanted to keep benznidazole (and the benefits that flow from FDA approval) away from Humanigen and its one-time owner, Martin Shkreli. This goal is belied by the facts: Chemo rebuffed Savant in 2013, before the voucher drastically changed the economics of developing benznidazole; Shkreli was removed from Humanigen *before* DNDi and Chemo Research agreed to join forces; and Humanigen then pledged publicly in the spring of 2016 that it would only sell its drugs at a reasonable price.

151. As a result of Defendants' misappropriation, Plaintiff could not obtain FDA approval of benzindazole, and lost the chance to obtain a voucher for future expedited review of another drug.

152. Plaintiff is thus entitled to receive damages for the loss of the voucher as a result of Defendants' misappropriation of the Sosa-Estani Study data in an amount to be

determined at trial, of not less than $200 million. Given that this misappropriation was malicious, Plaintiff also seeks exemplary damages of not less than $200 million.

COUNT V

Unjust Enrichment

153. Plaintiff repeats and realleges, as if set forth fully herein, the allegations in the preceding paragraphs of this Complaint.

154. Defendants were aware that the Sosa-Estani Study was the key to obtaining FDA approval of benzindazole. However, Savant held exclusive rights to that data, and did not authorize Defendants to use it in any way.

155. With no legal way to obtain the Sosa-Estani Study, Defendants induced IECS, with promises of millions of dollars to IECS and a plum job for Sosa-Estani, to ignore their existing obligations to Savant and give them the valuable data so they could win FDA approval and the voucher.

156. Savant, ignorant of Defendants' wrongdoing, had proceeded to partner with Humanigen and take all reasonable steps to prepare an NDA for benzindazole. It was not until March 2016, when Sosa-Estani refused to make his study data available to Savant, that the scope of Defendants' wrongful acts was revealed.

157. By obtaining this data and winning FDA approval, Defendants have unjustly enriched themselves at Savant's expense. Defendants, not Savant, have won the FDA expedited review voucher, which has a market value measured in the hundreds of millions of dollars. Equity and good conscience therefore require restitution.

158. Plaintiff is thus entitled to receive damages for the loss of the voucher as a result of Defendants' unjust enrichment in an amount to be determined at trial, of not less than $200 million.

RELIEF REQUESTED

159. Plaintiff respectfully requests an award:

(a) Transferring the rights to the priority review voucher for benznidazole to Savant;

(b) Placing the proceeds from United States sales of benznidazole in a constructive trust; granting compensatory damages in an amount to be determined at trial but believed to be in excess of $200 million;

(c) Interest on any award at the maximum allowable rate; and

(d) Granting such other relief, including punitive or exemplary damages and attorneys' fees, as may be just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands trial by jury on all issues so triable.

DATED: ___, 2020
New York, New York

Respectfully submitted:

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